

In the outstanding Office Action, the Examiner objected to the disclosure due to the PCT abstract; rejected claims 1 – 12, 15 – 32 and 35 – 55 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,830,549 to Bui et al. (hereinafter referred to as “the Bui et al. ‘549 patent”); and rejected claims 13, 14, 33 and 34 under 35 U.S.C. §103(a) as being unpatentable over the Bui et al. ‘549 patent in view of U.S. Patent No. 7,041,063 to Abreu (hereinafter referred to as “the Abreu ‘063 patent”).

Applicant submits that the Examiner has apparently examined the set of claims filed with the PCT application and mistakenly included in the U.S. PTO publication. Please note that a preliminary amendment cancelling claims 1 – 55 and introducing claims 56 – 97 was filed on July 28, 2005 (a copy of the stamped filing receipt and the accompanying documents are submitted in an Appendix to this paper). To avoid confusion, in this Response the number of each claim cited to by the Examiner is referred to as “PCT Claim...” and the number of the identical claim filed in the preliminary amendment is referred to as “Filed Claim....”

By this Response, Applicant traverses the prior art rejections. It is respectfully submitted that no new matter has been introduced to this application.

Objection to the Disclosure

The Examiner the Examiner objected to the disclosure due to the PCT abstract.

Response

Along with this Response, a copy of the preliminary amendment filed on July 28, 2005 is submitted. Applicant respectfully requests that the amendments to the Abstract be entered and submits that the objection to the specification is moot. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

Rejections Under 35 U.S.C. §102(e)

The Examiner rejected claims 1 – 12, 15 – 32 and 35 – 55 as being anticipated by the Bui et al. '549 patent; and the Examiner rejected claims 13, 14, 33 and 34 as being unpatentable over the Bui et al. '549 patent in view of the Abreu '063 patent.

Response

Along with this Response, the preliminary amendment of July 28 showing that claims 1 – 55 have been previously cancelled is submitted. Thereby rendering the claim rejections are moot. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection to claims 1 – 55.

MISCELLANEOUS

Background:

The present application generally discloses a life detector, which is a device adapted to determine the life status or health status of an organism or part thereof via the use of physiological sensor(s). One example of an intended use of the device is to equip security or search and rescue personnel therewith, so that in an emergency situation the life or health status of a victim or multiple victims of an incident may be quickly attained. Notably, the device is adapted to provide a qualitative diagnosis, which informs a user thereof of the life status or health status of a victim in layman's terms, so that the user need not be a medical professional.

The Bui et al. '549 patent generally describes a device including an "ambulatory patient monitor" worn by a patient/user for sensing and recording various physiological data via sensors attached thereto

and a larger “communications unit,” usually located somewhere in the home of the patient, which may be coupled to the patient monitor for receiving, storing and transmitting the recorded data from the patient monitor to a “remote controller.” The remote controller is, for example, a computer of a caregiver (i.e. a medical professional) at a distant location. The caregiver sends a “predetermined range” for each of the sensors to the patient monitor via the remote controller and communications unit. When the physiological sensors of the patient monitor sense a value outside its predetermined range an alarm is triggered, alerting the patient to contact the caregiver via the communications unit.

The purposes of the devices of the presently claimed invention and the Bui et al. ‘549 patent differ, therefore so does the operation thereof. As the patient monitor of the Bui et al. ‘549 patent is designed to monitor a user who is initially assumed to be within a predetermined range of some sort of healthy state, it provides an alarm only when values sensed fall outside of that range. This alarm is for alerting a healthcare professional automatically or via communications with the patient, so that the professional may diagnose the patient based on data recorded and transmitted from the sensors of the patient monitor. In contrast, the life detector of the Application is adapted to provide a diagnosis of a patient having an initially unknown state, to someone who may not have a medical background, and therefore it provides a diagnosis based on values sensed within predetermined ranges which indicate an understandable condition, even to a layperson. Additionally, the life detector of the Application is adapted to disregard values which fall outside of the predetermined ranges as it is designed to search for signs which indicate life.

PCT Claim 1 (Filed Claim 56) Independent PCT Claim 44 (Filed Claim 96)

In the Examiner's rejection of PCT Claim 1, portions of the Bui et al. ‘549 patent cited refer to the patient monitor only, and therefore Applicant assumes that the Examiner considers the patient monitor of

the Patent to be equivalent to the invention defined in PCT Claim 1 of the Application.

PCT Claim 1 generally refers to a life detector for determining whether an organism or part thereof suits a life condition predefined by a set of ranges. The life detector comprises a sensor unit adapted to detect values of at least two physiological parameters of an organism or part thereof, and a processor for receiving and processing the sensed values to provide a qualitative diagnosis based thereon and which is adapted to disregard values outside of the set of ranges.

PCT claim 1 recites “[a] life detector adapted to be used to determine whether an organism or part thereof suits a life condition predefined by a set of ranges, each for a physiological parameter and each characterizing said life condition, the detector comprising a sensor unit adapted to sense at least two of said physiological parameters and to generate signals indicative of their values, a processor for receiving and processing said signals to arrive at said values, the processor further being adapted to disregard any value falling outside the range of the respective parameter and to produce a qualitative diagnosis based on values falling within its range, the diagnosis being indicative of whether said organism or part thereof suits said life condition, the detector further comprising indication means adapted to indicate said diagnosis.”

Please note that independent PCT Claim 44 (filed claim 96) is a method claim similar to PCT claim 1. PCT claim 44 recites “[a] method for determining whether an organism or part thereof suits a life condition predefined by a set of ranges, each for a physiological parameter and each characterizing said life condition, including: - sensing at least two of said parameters of the organism and generating signals indicative of their values; - receiving and processing said signals to arrive at said values, including disregarding any value falling outside the range of the respective parameter; - producing a qualitative diagnosis based on any value falling within the range for its parameter, the diagnosis being indicative of whether the organism suits said life condition; - indicating said diagnosis.”

The Bui et al. '549 patent discloses a patient management system that has a programmable patient monitor for monitoring and recording physiological conditions of a patient and a plurality of physiological condition sensors and a communications unit. Each of the patient monitoring sensors detects a particular physiological condition of the patient, such as core temperature. To provide communication with a caregiver via a remote controller at the caregiver's location, a communications unit is disposed in the facility. When the patient connects the patient monitor to the communications unit, the patient can communicate with the caregiver at the remote location.

The Abreu '063 patent discloses a contact device placed on a person's eye in order to detect physical and chemical parameters of the body as well as the non-invasive delivery of compounds according to these physical and chemical parameters, with signals being transmitted continuously. One of the parameters to be detected includes non-invasive blood analysis utilizing chemical changes and chemical products that are found in the conjunctiva and in the tear film. A transensor mounted in the contact device lying on the cornea or the surface of the eye is capable of evaluating and measuring physical and chemical parameters in the eye including non-invasive blood analysis.

In contrast to the presently claimed invention, neither the Bui et al. '549 patent, or the Abreu '063 patent, nor the combination thereof discloses, teaches or suggests a "processor being adapted to disregard any value falling outside the range of [a] respective parameter" as recited in independent PCT claim 1 and as similarly recited in PCT claim 44. The Bui et al. '549 patent discloses that "if the detected signal is outside the predetermined range, a patient alarm signal is generated." (col. 3, lines 59-61). Therefore, the Patent explicitly teaches that values detected outside the predetermined range cause alarms and are not disregarded as in the presently claimed invention. Thus, for at least this reason, the presently claimed invention is not anticipated by the Bui et al. '549 patent. Moreover, combining the Abreu '063 patent with the Bui et al. '549 patent does not cure the deficiencies of the Bui et al. '549 patent as it lacks the

feature necessary to anticipate the presently claimed invention or render it obvious.

In further contrast to the presently claimed invention, neither the Bui et al. '549 patent, the Abreu '063 patent, nor the combination thereof discloses, teaches or suggests the processor also being adapted to "produce a qualitative diagnosis based on values..." of the respective parameter" as recited in PCT claim 1 (filed claim 56) and as similarly recited in PCT claim 44 (filed claim 96). With respect to this feature, the present Application defines a "qualitative diagnosis" on page 5 of the specification as "a general interpretation of an organism's life status or a victim's health status in a manner that may be understood by an operator who is not... a medical professional." In this connection, it should be noted that the Examiner cites the ECG sensor denoted by the numeral 217 in Figs. 1 and 3A of the Bui et al. '549 patent, against PCT Claim 1, and thus apparently considers this sensor to be equivalent to a part of the sensor unit of the life detector of the Application. Notably, the Bui et al. '549 patent discloses that "All analysis or processing of ECG data is done by the caregiver" (col. 14, lines 36 – 37). Additionally, the Bui et al. '549 patent defines the "caregiver" as a "healthcare professional" (Col. 1, line 29). Therefore, the patent does disclose a sensor unit which produces a qualitative diagnosis, as defined in the specification of the present application.

In yet further contrast to the presently claimed invention, neither the Bui et al. '549 patent, nor the Abreu '063 patent, or the combination thereof discloses, teaches or suggests "a qualitative diagnosis based on values falling within its range [of the respective parameter]" as recited in PCT claim 1 (filed claim 56) and as similarly recited in PCT claim 44 (filed claim 96). This feature, which defines values of sensed physiological parameters falling within the range of a respective parameter based on which quality diagnosis is performed, being indicative of said life condition, is not disclosed by the Bui et al. '539 patent because it does not produce any diagnosis, and *a fortiori*, qualitative diagnosis, for values detected within the range of a respective parameter being indicative of a life condition. Thus, for at least this additional

reason, the presently claimed invention is not anticipated by the Bui et al. '549 patent.

PCT Claim 2 (Filed Claim 57) and Dependent Claim 45 (Filed Claim 97)

Dependent claim 57 (PCT Claim 2) recites a life detector “according to Claim 1, wherein the range of each of said at least two parameters includes a predefined set of sub-ranges, each characterizing a particular state within said life condition and each having a predefined priority level with respect to said life condition, said processor being further adapted to determine the particular sub-range in which the value of each parameter falls and the state characterized by said sub-range, and to produce a qualitative diagnosis based only on the state having the highest priority level.” Dependent PCT Claim 45 is a method claim reciting features similar to dependent claim 57 (PCT Claim 2).

In contrast to the presently claimed invention, the Bui et al. '549 patent cited against PCT Claim 2, do not disclose, teach or suggest “a predefined set of sub-ranges, each characterizing a particular state within said life condition and each having a predefined priority level with respect to said life condition” as recited in claim 57 (PCT claim 2). Further, the Bui et al. '549 patent does not disclose, teach or suggest “a qualitative diagnosis based only on the state having the highest priority level” as also recited in claim 57 (PCT claim 2).

In the Office Action, the Examiner cites col. 20, lines 51-67, col. 21, lines 1 – 7 and col. 22, lines 33 – 49 of the Bui '549 patent for disclosure of the phrase “the priorities.” Applicant therefore assumes that the Examiner considers the priority level for the sub-ranges of the parameters to be equivalent to the “priorities” mentioned in the cited portions. Notably, each “priority level” recited in claim 57 (PCT Claim 2) refers to a sub-range of the at least two parameters, and these parameters are defined in PCT Claim 1 as being “physiological parameters.” Therefore the feature of a priority level in claim 57 (PCT Claim 2) is not disclosed by the Bui et al. '549 patent because the portions of the Bui et al. '549 patent cited by the

Examiner describe priorities for ALARMS, ALERTS and EVENTS of the patient monitor, (col. 20, lines 53-55, col. 21, lines 1-7), and alerts and events are not attributed to sub-ranges of physiological parameters as “an ALERT or ALERT CHECK is a system test which checks the performance of the sensors and other system components against a set of pre-determined test limits,” (col. 20, lines 4 – 6), and events are a mode of the patient monitor initiated by a patient (Col. 22, lines 32 – 35). The Abreu ‘063 patent is silent with respect to this feature and, since this feature is not disclosed in the Bui et al. ‘549 patent, the presently claimed invention is patentable over the cited references and any combination thereof.

PCT Claim 7 (Filed Claim 62)

PCT Claim 7 defines a “processor and said indication means being adapted to indicate said diagnosis to such human operator who is not a medical professional.” The Examiner states that the Bui et al. ‘549 patent discloses such, because the detector is carried by a patient/user. However, Applicant traverses this position as the Bui et al. ‘549 patent defines the caregiver as a “healthcare professional” (col. 1, line 29), and even if the patient monitor of the Bui et al. ‘549 patent were to produce a qualitative diagnosis, which, as argued above, it does not. The Bui et al. ‘549 patent indicates, as mentioned above, that the ECG sensor 217, which the Examiner cites with respect to PCT Claim 1 as a part of the detector, is clearly intended not to indicate any such diagnosis to the patient/user but rather to the healthcare professional. The Abreu ‘063 patent is silent with respect to this feature and, since this feature is not disclosed in the Bui et al. ‘549 patent, the presently claimed invention is patentable over the cited references and any combination thereof.

PCT Claims 16, 17, 18 and 19 (Filed Claims 71, 72, 73 and 74)

PCT Claim 16, from which claims 17, 18 and 19 depend, recites a life detector “comprising a rod with said sensor unit attached thereto.” The Examiner cites Figs. 21A and 21B of the Bui et al. ‘549 patent against this claim, however the description of these diagrams (col. 17, lines 7-19) clearly describes a core temperature sensor 216 which “includes a cable 322.” Therefore the Bui et al. ‘549 patent does not disclose a rod but rather a cable. Additionally, even if the cable could be considered a rod, which Applicant disputes, it is not attached to the sensor unit but is rather included as part of the sensor unit.

As there is no rod disclosed, taught or suggest in the Bui et al. ‘549 patent, the presently claimed invention is patentable thereover. The Abreu ‘063 patent is silent with respect to this feature and, since this feature is not disclosed in the Bui et al. ‘549 patent, the presently claimed invention is patentable over the cited references and any combination thereof.

PCT Claim 21 (Filed Claim 76)

PCT Claim 21 recites a life detector as being “in the form of a flexible cable with said sensor unit attached to one end of said cable.” The Examiner cites Fig. 2 of the Bui et al. ‘549 patent against this claim, however the device in Fig. 2 does not appear to be in the form of a cable. Furthermore, in Fig. 2 of the Bui et al. ‘549 patent, each of the sensors, and in particular sensor 214, is not shown to be attached to one end of a cable. The Abreu ‘063 patent is silent with respect to this feature and, since this feature is not disclosed in the Bui et al. ‘549 patent, the presently claimed invention is patentable over the cited references and any combination thereof.

PCT Claim 28 (Filed Claim 83)

PCT Claim 28 recites a life detector as “a general purpose programmable device (PD),” however

it is not clear where this feature is disclosed, taught or suggested by the cited prior art. The Office Action merely refers to a “programmable monitor 20” of the Bui et al. ‘549 patent while not relating it to “a general purpose programmable device (PD),” as recited in PCT claim 28 (filed claim 83) and cites sensors 214, 215, 216 and 217 and Figs. 1 to 3. The Abreu ‘063 patent is silent with respect to this feature and, since this feature is not disclosed in the Bui et al. ‘549 patent, the presently claimed invention is patentable over the cited references and any combination thereof.

PCT Claims 38 and 39 (Filed Claims 90 and 91)

PCT Claim 38 recites a life detector as being adapted to treat an organism. The Examiner cites text in Col. 1 of the Bui et al. ‘549 patent against this claim. Additionally, the Examiner cites Col. 6, lines 34-38, which discloses that a “communications unit can also monitor other devices, such as an infusion pump....” However, this does indicate that the infusion pump is part of the detector, or that it is controlled by the communications unit, merely that the communications unit is able to monitor it. The Abreu ‘063 patent is silent with respect to this feature and, since this feature is not disclosed in the Bui et al. ‘549 patent, claim 38 is patentable over the cited references and any combination thereof.

With regard to PCT Claim 39, which defines the life detector as further comprising other means of treatment, the Examiner raises the same argument regarding the infusion pump of the Bui et al. ‘549 patent, and therefore the counter-argument above is also valid with respect to this claim. Additionally, the other devices indicated by the Examiner in Cols. 3 and 4 of the Patent, as if they are for giving treatment, seem to only be adapted to transmit “physiological signals” (Col. 3, line 34), and hence do not appear to cause treatment of an organism or part thereof. The Abreu ‘063 patent is silent with respect to this feature and, since this feature is not disclosed in the Bui et al. ‘549 patent, claim 39 is patentable over the cited references and any combination thereof.

PCT Claims 40-43 (Filed Claims 92-95)

PCT Claim 40 defines the sensor unit as comprising a permanent base and at least one changeable sensor. The Examiner's comments are not clear with regard to what he considers the permanent base. As the Examiner makes reference in some of the PCT Claims 40-43, to the infusion pump, which is not a sensor and is only mentioned as being connectable to the communications unit, which seems unlikely to be part of the sensor unit, Applicant respectfully requests that the Examiner clarify his objections with regards to these claims.

CONCLUSION

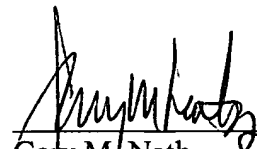
In light of the foregoing, Applicant submits that the application is now in condition for allowance. If the Examiner believes the application is not in condition for allowance, Applicant respectfully requests that the Examiner contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

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